K100896

JUN 17 2010

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Gyrus ACMI® HALO PKS Cutting Forceps®

General Information

Manufacturer:	Gyrus ACMI, Inc. 136 Turnpike Road Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Lorraine Calzetta Senior Regulatory Affairs Specialist
Date Prepared:	19 Apr 2010

Device Description

Classification Name:	Electrosurgical Cutting & Coagulation Device and Accessories (21 CFR 878.4400), Class II General& Restorative Surgery Panel
Trade Name:	Gyrus ACMI® HALO PKS Cutting Forceps®
Generic/Common Name:	Electrosurgical device for cutting and coagulation

Predicate Device

Gyrus Bipolar Cutting Forceps cleared under K023492
Gyrus General Surgery Generator cleared under K050550

Intended Uses

The Gyrus ACMI® HALO PKS Cutting Forceps is indicated for electrosurgical coagulation, mechanical cutting and grasping of tissue during the performance of laparoscopic and open general surgical procedures when used in conjunction with the Gyrus ACMI General Surgery Generator (G400).

Product Description

The Gyrus ACMI®HALO PKS Cutting Forceps is a bipolar electrosurgical device that may be utilized in minimally invasive surgery for general endoscopic use to grasp, coagulate, transect, dissect and retract tissue. The Gyrus ACMI® HALO PKS Cutting Forceps is a single use, sterile accessory, to be used in conjunction with the bipolar outputs of the Gyrus General Surgery Generator (G400).

The Gyrus ACMI®HALO PKS Cutting Forceps is a modification of the Gyrus Bipolar Cutting Forceps and includes hand switching capabilities and a redesigned handle based on human factors considerations. The device handle has been ergonomically redesigned with additional areas of soft polymer around the device where the user contacts it. Thumb tabs for advancing the blade that were present on the predicate have been replaced with a pistol like trigger for user comfort. The ratchet mechanism blade activation has been redesigned and the latch mechanism has been moved to a place that allows single hand use. The HALO Cutting Forceps includes new features including hand activation, and a mode switch (Select Button) on the handpiece that allows the user to select either of up to two devices attached to the G400 generator at any one time. Selection of either device is indicated by the illumination of a green LED on top of the handpiece showing that the device has been selected. The jaws are identical as those found on the predicate Gyrus Bipolar Cutting Forceps except that they are selectively rotatable via a rotation wheel on the device which allows for rotation of the jaws about the device shaft.

Comparison of Technological Characteristics of Device to Predicate Device

The Gyrus ACMI® HALO PKS Cutting Forceps is a single use, sterile accessory for use with the G400 Generator only, and is intended to provide the same performance as the predicate Gyrus Bipolar Cutting Forceps, but with the added utility of hand switching, rotation and attention given to user comfort The modified device and the currently marketed device share the same intended use, same operating principle, same radiofrequency generator (G400), similar patient contacting materials and same processes of packaging and sterilization. The distal end of the device has not changed. The jaws are identical as those found on the predicate Gyrus Bipolar Cutting Forceps, except that they are selectively rotatable via a rotation wheel on the device which allows for rotation of the jaws about the device shaft. The Gyrus ACMI® HALO PKS Cutting Forceps may be activated via the handpiece switch or footswitch, whereas the predicate could only be activated via a footswitch.

Summary of Performance data

Performance testing was utilized to establish the performance characteristics of the modifications of the device and determine substantial equivalence to the predicate. Performance testing includes biocompatibility testing, sterility testing, shelf life testing, design verification and validation (non-clinical bench testing and preclinical testing)

The patient contact portions of the device have been evaluated for biocompatibility and comply with the requirements of ISO 10993-1.

The Gyrus ACMI® HALO PKS Cutting Forceps is a Single use, sterile device and has been tested to ensure a SAL of 10^{-6} and comply with the requirements of ISO 11135-1.

The device was tested to demonstrate compliance with the following electrical safety standards:

IEC 60601- Medical Electrical Equipment - Part 1: General Requirements for Safety.

IEC 60601-Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment.

IEC 60601-- Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility.

Non-clinical bench testing and preclinical performance testing show that the device performance is substantially equivalent to the predicate, and that the modifications raise no new issues of safety and effectiveness.

Summary of Safety and Effectiveness

The proposed modified Gyrus ACMI® HALO PKS Cutting Forceps®, as described in this submission, is substantially equivalent to the predicate device. The intended use and basic scientific technology of the device are not changed, nor is the intended user or distal end design. The proposed modifications in design do not significantly affect the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gyrus Acmi, Inc.
% Ms. Lorraine Calzetta
Senior Regulatory Affairs Specialist
136 Turnpike Road
Southborough, Massachusetts 01772

JUN 17 2010

Re: K100896
Trade/Device Name: Gyrus ACMI® HALO PKS Cutting Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 18, 2010
Received: May 18, 2010

Dear Ms. Calzetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Gyrus ACMI® HALO PKS Cutting Forceps

Indications for Use:

The Gyrus ACMI® HALO PKS Cutting Forceps are indicated for electrosurgical coagulation, mechanical cutting and grasping of tissue during the performance of laparoscopic and open general surgical procedures when used in conjunction with the Gyrus ACMI General Surgery Generator (G400).

Prescription Use: __ **X** __ AND/OR Over-the-Counter Use: _____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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